



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Pediatric Clinical Investigator Training; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development are announcing a 2-day public workshop entitled "Pediatric Clinical Investigator Training." The purpose of this workshop is to provide investigators with training and expertise in designing and conducting clinical trials in pediatric patients that will lead to appropriate labeling. Although we have learned a lot about conducting pediatric trials over the past two decades, there are still challenges that need to be addressed. The training course is intended to provide investigators with: (1) A clear understanding of some of the challenges of studying products in the pediatric population, including: Pediatric study design, neonates, biomarkers, endpoints, orphan drugs and rare disease trial design, formulations; (2) an overview of extrapolation as it relates to the pediatric population; and (3) an overview of ethically appropriate methods related to the design of clinical trials in the pediatric population.

DATES: The public workshop will be held on September 12 and 13, 2016, from 8 a.m. to 4 p.m. Registration to attend the workshop should be completed by September 6, 2016. (See the SUPPLEMENTARY INFORMATION section for instructions).

ADDRESSES: This public workshop will be held at the DoubleTree Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, terrie.crescenzi@fda.hhs.gov; or Betsy Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, elizabeth.sanford@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) made permanent the pediatric initiatives, Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act, which have stimulated pediatric research over the past two decades. The National Institutes of Health section of BPCA legislation, however, is due for reauthorization in 2017. Though much progress has been made, pediatric trials for the purpose of developing product use information are still performed less frequently than adult trials. As such, current standards for trials are much more oriented to adult scientific, ethical, and clinical processes. This situation is due, in part, to the fact that pediatric trials have both scientific challenges and unique attributes and requirements which must be met if the data are to be accepted or used by FDA.

The development of safe and effective products in the pediatric population presents many challenges. These challenges include trial design, appropriate endpoints, extrapolation of data from adults, and ethical issues. It is extremely important that pediatric researchers recognize and understand the challenges and differences between the standards for adult trials and pediatric

trials. Researchers are responsible for ensuring the safe and ethical treatment of pediatric patients and obtaining adequate and reliable data to support regulatory decisions. There is a critical need for further pediatric research on medical products to obtain additional data which will help ensure that these products are safe and effective in the pediatric population. Much of the progress which has been made in obtaining proper therapeutic information in pediatrics has occurred in the older and more populous pediatric populations. The challenge of obtaining data from non-verbal children, neonates, and for conditions existing in limited populations is much more difficult. This need reinforces our responsibility to educate clinical investigators to assure that children are only enrolled in research that is scientifically necessary, ethically sound, and designed to meet the challenges of review by FDA.

II. Workshop Attendance and Participation

If you wish to attend this workshop, visit <http://pedsinvesttrain.eventbrite.com>. Please register by September 6, 2016. Those who are unable to attend the workshop in person can register to view a live Webcast of the workshop. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration will also require your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited so early registration is recommended. Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the workshop will be based on space availability. Persons attending the workshop are advised that FDA is not responsible for providing access to electrical outlets.

Registration information, the agenda, and additional background materials can be found at <http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm>.

Webcast: The workshop will be Webcast live and available on the Internet.

The live Webcast on September 12, 2016, will be available at:

<https://event.webcasts.com/starthere.jsp?ei=1093258>. After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (note that it is different from the morning's session):

<https://event.webcasts.com/starthere.jsp?ei=1093259>. On September 13, 2016, the live Webcast will be available at: <https://event.webcasts.com/starthere.jsp?ei=1093263>. After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (note that it is different from the morning's session): <https://event.webcasts.com/starthere.jsp?ei=1093265>. The Webcast will only be for listening and there will not be an opportunity for Webcast participants to speak. The Webcast will be posted after the workshop at:

<http://wcms.fda.gov/FDAgov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm?ssSourceSiteId=null&SSContributor=true>, approximately 30 days after the workshop.

If you need special accommodations due to a disability, please contact Betsy Sanford (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Dated: June 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-14230 Filed: 6/15/2016 8:45 am; Publication Date: 6/16/2016]